The MetaNeb® System

For the Treatment & Prevention of Atelectasis and Retained Secretions

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Disclosures

- Anne Snyder, RRT
- Clinical Education Specialist
- Respiratory Health Division; Hill-Rom®
- Makers of;
  - The MetaNeb® System
  - The Vest® Airway Clearance System

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The MetaNeb® System Presentation

Objectives

1. Identify conditions and patient populations at risk for pulmonary complications
2. Discuss challenges to providing airway clearance and lung expansion therapy
3. Understand the mechanisms of action of The MetaNeb® System
4. Gain insight into which patients in the hospital may benefit from MetaTherapy® Treatments
5. Review sample literature

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Factors that Affect Airway Clearance

Impaired mucociliary clearance
- Artificial airways/mechanical ventilation
- Thick and/or hypersecretions
- Immobility
- Abnormal mucous flow

Poor, ineffective or absent cough
- Pain
- Decreased muscle function
- Diaphragm impairment

Decreased ventilation/lung volumes
- Impaired gas exchange
- Alveolar impairment
- Absence of periodic deep breaths/sighs
- Inadequate airflows

Decreased respiratory drive
- Sedation
- Medications
- Neuro injuries
- Muscular dysfunction

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Identifying Patients at Risk

Procedure-Related Risk Factors for Pulmonary Complications
- Duration of surgery[1,2]
- Type of anesthesia / sedation[1,2]
  - Impairment of respiratory muscle function
  - Alterations in respiratory drive
  - Decreased lung volumes
- Surgical site[1]:
  - Thoracic resections
  - Coronary bypass grafting
  - Upper abdominal surgeries
  - Trauma -related surgeries
  - Head and neck procedures
  - Some orthopedic procedures
- Post surgical pain and splinting[1]

[1]Yoder MA et al Perioperative Pulmonary Management, August 15, 2011. available at http://emedicine.medscape.com/article/2845983-overview#aw2aab6b8
[2]Smetana GW "Postoperative pulmonary complications: An update on risk assessment and reduction" Cleveland Clinic Journal Of Medicine Volume 76 Supplement 4 November 2009

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Identifying Patients at Risk

Patient-Related Risk Factors for Pulmonary Complications
- Age and general health[1,2]
- Smoking history[2]
- Immunosupression[2]
- Recent respiratory infection[2]
- Productive cough/wheezing within 5 days of surgery[2]
- Immobility or difficult to move[3]
- Obesity[2]
- Weight loss[3]
- Trauma
  - Fractured ribs / flail chest[4]
  - Head injury[4]
  - High level SCI[5]

[1]Jin F, Chung F. Minimizing perioperative adverse events in the elderly Br. J. Anaesth. (2001) 87 (4): 608-624 doi:10.1093/bja/87.4.608
[2]Yoder MA et al Perioperative Pulmonary Management, August 15, 2011. available at http://emedicine.medscape.com/article/2845983-overview#aw2aab6b6
[3]Smetana GW "Postoperative pulmonary complications: An update on risk assessment and reduction" Cleveland Clinic Journal Of Medicine Volume 76 Supplement 4 November 2009
[4]Lee K, Rincon F. "Pulmonary Complications in Patients with Severe Brain Injury" Critical Care Research and Practice Volume 2012, Article ID 207247, 8 pages doi:10.1155/2012/207247
[5]Berlly M et al «Respiratory Management During the First Five Days After Spinal Cord Injury" J Spinal Cord Med. 2007;30:309–318

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Identifying Patients at Risk

Additional Risk Factors: Patients with Chronic Disease

- Chronic Lung Disease such as:[1]
  - COPD[1]
  - Asthma[1]
  - Cystic Fibrosis[2]
  - Bronchiectasis[2]
- Chronic Neurologic Diseases
  - Diseases of the neurologic system, including brain, spinal cord, motor nerves and muscles may lead to[3,4]:
    - Respiratory muscle or diaphragm dysfunction
    - Spinal / thoracic deformity
    - Hypoventilation/Ineffective cough
    - Bulbar dysfunction
    - Dysphasia and aspiration

[1]Yoder MA et al Perioperative Pulmonary Management, August 15, 2011. available at http://emedicine.medscape.com/article/284983-overview#aw2aab6b4
[2]Chang AB, Bilton D "Exacerbations in cystic fibrosis 4 - Non-cystic fibrosis bronchiectasis" *Thorax* 2008;63:269-270.doi:10.1136/thx.2006.060913
[3]Bendit J, Boitano L "Pulmonary Issues in Patients with Chronic Neuromuscular Disease", American Journal of Respiratory and Critical Care Medicine, Vol. 187, No. 10 (2013), pp. 1048-1057.
[4]Schroth M "Special Considerations in the Respiratory Management of Spinal Muscular Atrophy" *Pediatrics* 2009;123:S245–S249

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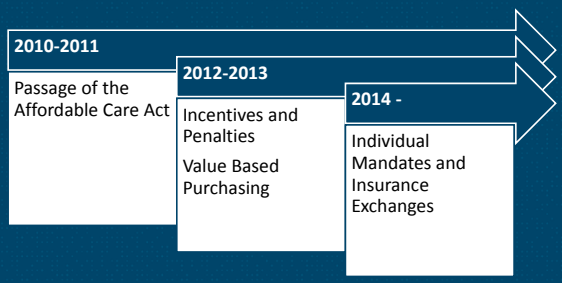
Highlights of Healthcare Reform



Department of Health and Human Services HHS.gov/HealthCare

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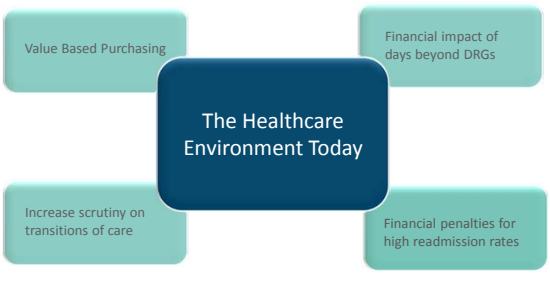
Current Situation in the Acute and Extended Care Settings


Value Based Purchasing
Financial impact of days beyond DRGs
The Healthcare Environment Today
Increase scrutiny on transitions of care
Financial penalties for high readmission rates

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Current Situation

- Respiratory complications are a major concern
  - Atelectasis appears in about 90% of all patients receiving general anesthesia & may last several days[1]
  - May contribute to pulmonary complications[1]
- Reimbursement environment is changing
- More focus on hospital acquired infections
- Growing awareness of prophylactic treatment of possible respiratory complications

Muders T, Wrigge H. New insights into experimental evidence on atelectasis and causes of lung injury. Best Prac Res Clin Anaesthesiol 2010; 24: 171–82[1]

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Where We Have Been…

Lung Expansion Therapy	Chest Physical Therapy (CPT)
Patient effort dependent • Coughing and deep breathing • Incentive Spirometry Devices • Some require patient effort • May be difficult to combine therapies • Disposable options not always available • Not all can be used with mechanical ventilation	12 position CPT[1] • To treat all lobes of the lungs • Positions should be held for 3 to 15 minutes[1] – 12 positions X 3 minutes = 36minutes – 12 positions x 15 = minutes = 180 minutes • Percussion • Vibration

[1]Bronchial Hygiene Guidelines Committee, American Association for Respiratory Care. AARC clinical practice guideline: postural drainage therapy. Respiratory Care 1991; 36: 1418 - 1426.

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Challenges in Current Practice

- Increasing demand for services
- Shortage of respiratory therapists
- Sicker and larger patients
- Multiple treatments / devices often required to meet all of patient's needs
- Multiple treatments may be time consuming and tiring for patients
- Patient effort / cooperation may be difficult if patient isn't able to:
  - Understand and follow directions (too young, too old, or confused)
  - Control their breathing – may be short of breath

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The MetaNeb® Systems Description

The MetaNeb® 3.0 System

The MetaNeb® Systems are therapeutic devices that use a systematic approach to enhance normal mucus clearance and resolve or prevent atelectasis.
For use in Acute Care and Long Term Care

The MetaNeb® 4.0 System

The MetaNeb® System User Manual (174432 REV 1) page 1-6
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The MetaNeb® System Description

The MetaNeb® System offers 3 therapies:

1. Continuous Positive Expiratory Pressure (CPEP)
   - Lung expansion therapy for the treatment and prevention of pulmonary atelectasis
2. Continuous High Frequency Oscillation (CHFO)
   - Secretions mobilization therapy
3. Aerosol Mode
   - Aerosol Therapy

Provides supplemental oxygen when used with compressed oxygen

"MetaTherapy® Treatment"

A combination therapy that provides aerosol therapy while alternating between CPEP Mode for lung expansion and CHFO Mode for airway clearance

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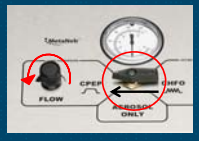
CPEP Mode
Continuous Positive Expiratory Pressure

Lung Expansion Mode

- Delivers flow during both inspiration and expiration to:
  - Provide continuous positive pressure
  - Provide positive expiratory therapy
  - Deliver aerosol
  - Treat and prevent pulmonary atelectasis



MetaNeb® 3.0 System

MetaNeb® 4.0 System

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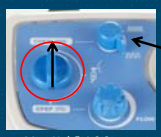
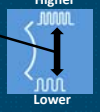
CHFO Mode
Continuous High Frequency Oscillation

Secretion Clearance Mode

- Maintains CHFO during inspiration and expiration
- Oscillates the airways with continuous pulses of positive pressure
  - Higher (230 BPM) or lower frequency (170 BPM)
- Delivers aerosol
- Mobilizes secretions

MetaNeb® 3.0 System





MetaNeb® 4.0 System

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Aerosol Mode

Delivery of aerosol only

– In this mode CPEP and CHFO are not available

MetaNeb® 3.0 System

MetaNeb® 4.0 System

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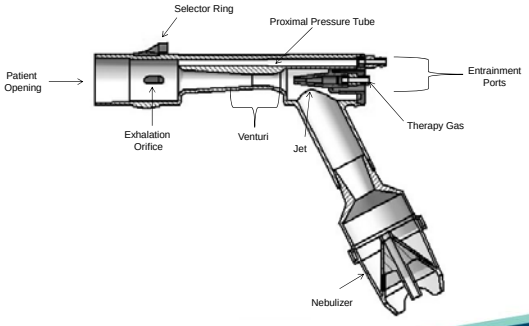
The MetaNeb® System Handset



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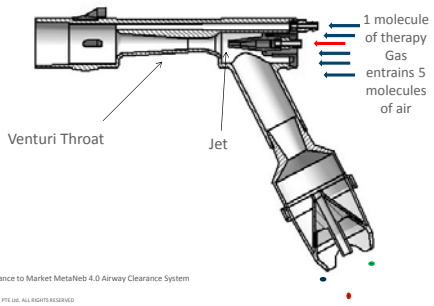
The MetaNeb® System

Entrainment of Ambient Air



FDA 510(k) Clearance to Market MetaNeb 4.0 Airway Clearance System
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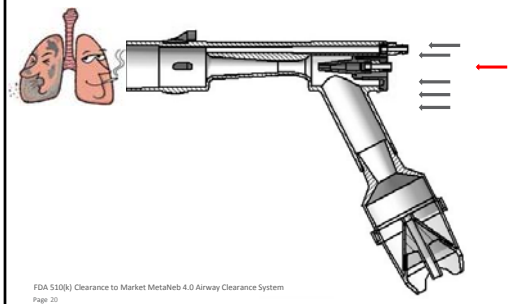
The MetaNeb® System

What Happens with Decreased Airway Compliance??



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Pre-Use Check Continued
Do this before to each use:

6. Occlude the patient opening of the handset.
   - Watch the pressure gauge. The average of pressure fluctuations should not be less than 15 and not more than 30 cm H2O.
7. Set the mode to CPEP.
8. Turn the **CPEP** flow adjuster counterclockwise to full flow. Make sure there is a peak pressure occurrence of not less than 20 and not more than 30 cm H2O.
9. If the device is not within the parameters specified above, do not use the unit. Contact Hill-Rom Technical Support to examine and repair the unit.

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The MetaNeb® System Circuit

- Single Patient Use Circuit for multiple treatment sessions
- Multiple patient interfaces
  - Mouthpiece

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The MetaNeb® System

Circuit with the Mouthpiece

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The MetaNeb® System Circuit

- Single Patient Use Circuit for multiple treatment sessions
- Multiple patient interfaces
  - Mouthpiece
  - Face Mask

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The MetaNeb® System

Circuit with a Face Mask

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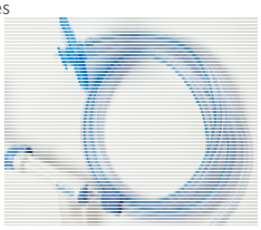
The MetaNeb® System Circuit

- Single Patient Use Circuit for multiple treatment sessions
- Multiple patient interfaces
  - Mouthpiece
  - Face Mask
  - Tracheostomy



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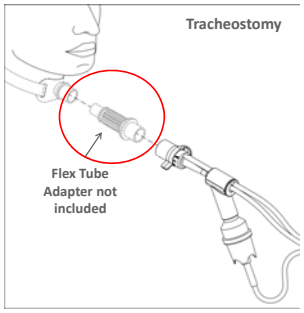
The MetaNeb® System
Circuit with a Tracheostomy



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The MetaNeb® System Circuit

- Single Patient Use Circuit for multiple treatment sessions
- Multiple patient interfaces
  - Mouthpiece
  - Face Mask
  - Tracheostomy
  - In-line

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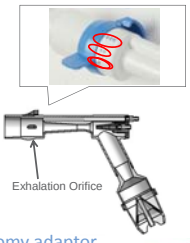
MetaTherapy® Treatment Protocol

Preparing the Controller

1. Follow institutional guidelines for infection control
2. Fill nebulizer with prescribed medications, if applicable
3. Set the mode selector switch to **CPEP**
4. Set selector ring to **"1"** dot position



Offers 3 Levels of Positive Expiratory Pressure **(PEP)**

"1 dot" position
- Largest opening with least resistance

"2 dot" position
- Smaller opening provides more resistance

"3 dot" position
- Smallest opening provides most resistance

Use with mouthpiece, face mask, or tracheostomy adaptor

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MetaTherapy® Treatment Protocol

Delivering a MetaTherapy® Treatment

1. Begin with **CPEP** Mode
   - Adjust flow and selector ring to patient comfortable / needs
2. Continue **CPEP** Mode ~ 2 ½ minutes
3. Move the **Higher/Lower** dial to **Higher**
4. Change mode to **CHFO** Mode
   - Higher/Lower dial may be moved to Lower to lower percussion rate and pressure if needed
5. Continue **CHFO** Mode for ~ 2 ½ minutes
6. Alternate between **CPEP** and **CHFO** ~ every 2 1/2 mins.
7. Continue for 10 minutes or until neb empty
8. When treatment complete, turn unit off, disconnect circuit, and store

Sample Protocols are for information & discussion purposes. The health care team is responsible for selecting appropriate treatment for the patient. Facilities are responsible for adopting their own protocols, & health care team should follow applicable facility protocols.

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The MetaNeb® System In-Line with Ventilator Protocol

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The MetaNeb® System In-Line with Ventilator Protocol

- Make a note of the current ventilator settings
- Put a spring-valve "tee" adapter into the inspiratory limb of the ventilator circuit
- Pt. should be in a position to maintain head of bed angle at > 30 degrees if possible
- Assess the breath sounds, heart and respiratory rates
- Set the mode to **CHFO** and select **Higher**

Sample Protocols are for information & discussion purposes. The health care team is responsible for selecting appropriate treatment for the patient. Facilities are responsible for adopting their own protocols, & health care team should follow applicable facility protocols.

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The MetaNeb® System

Circuit for in-line use

Remove selector ring

Install black occlusion ring

Use the adaptor (15 mm X 22 mm) to connect handset to the spring-valve tee adapter

(Follow instructions stated in user manual)
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The MetaNeb® System - Black Occlusion Ring

Insert into spring-loaded T-piece adapter

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The MetaNeb® System In-Line with Ventilator Protocol
During the Treatment

- Proceed with the **CHFO** in-line therapy for approximately 10 minutes
  - There is no need for **CPEP**, as this therapy is accomplished with the ventilator
- Monitor the patient's responsiveness to treatment
- Adjust ventilator alarms as necessary during therapy
- Suction secretions as necessary during treatment
  - Do not leave the patient during the therapy and be prepared to suction
  - As secretions mobilize it is not uncommon for plugs to momentarily occlude the upper airways

Sample Protocols are for information & discussion purposes. The health care team is responsible for selecting appropriate treatment for the patient. Facilities are responsible for adopting their own protocols, & health care team should follow applicable facility protocols.

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The MetaNeb® System In-Line with Ventilator Protocol
Post-Treatment

- Remove the handset, cap the spring-valve tee adapter, then turn the master switch **OFF**
- Empty medication from nebulizer and store in accordance with institutional protocol
- Return the ventilator alarms and mode to their previous settings
- Monitor and document the patient's tolerance during and after the treatment (HR, Sp02, Bp, Auscultation)

Sample Protocols are for information & discussion purposes. The health care team is responsible for selecting appropriate treatment for the patient. Facilities are responsible for adopting their own protocols, & health care team should follow applicable facility protocols.

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The MetaNeb® Systems

Absolute Contraindications	Relative Contraindications	Possible Adverse Reactions
–Untreated tension pneumothorax –Untrained or unskilled operator	–History of pneumothorax –Pulmonary air leak –Recent pneumonectomy –Pulmonary hemorrhage –Myocardial infarction –Vomiting	–Hyperventilation –Gastric distension –Decreased cardiac output –Increased intracranial pressure –Increased air trapping – Hyperoxygenation –Pneumothorax –Pulmonary air leak –Pulmonary hemorrhage

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Cleaning and Disinfecting

- Cleaning the circuit
  - To help prevent cross-contamination, replace the SPU circuit between patients
  - Replace circuit between patients, when damaged or when visibly soiled
  - Do not disinfect or sterilize the circuit for reuse with more than one patient
  - The circuit is intended for a maximum use of 30 treatments or 7 days of use
- Cleaning the Controller and Stand
  - Wipe down the controller and stand with a soft cotton cleaning pad that is moistened with the cleaner
  - Do not use excessive liquid or harsh cleaners
  - Do not immerse the controller in water or let liquids enter the controller

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Assessment of Outcome

- **Frequency**
  - **Common strategy ranges from two(2) to four(4) times daily**
  - **In-line use with a ventilator ranges from four(4) to eight(8) times daily**
  - **Frequency determined by patient's response to therapy**
- **Therapy will be discontinued per facility protocol or when one of these occur:**
  - **Secretion clearance is <5 cc per treatment for a 24 hour period**
  - **The post therapy chest exam demonstrates absence of retained secretions and atelectasis**
  - **Breath sounds have become clear or have improved**

(Follow instructions stated in user manual)
The MetaNeb® System User Manual (174432 REV 1) page 13-18

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Algorithms

Policies & Procedures

PROTOCOLS

Literature
The MetaNeb® System

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The MetaNeb® System Literature
Respiratory Care - 2009 OPEN FORUM Abstracts

The Use Of a Progressive Pulmonary Protocol in an Oncologic Intensive Care Unit
Laura G. Withers, Clarence G. Finch, Kristen J. Price, Quan M. Nguyen; Respiratory Care and Critical Care,
The University of Texas MD Anderson Cancer Center, Houston, TX

Overview:

A progressive pulmonary protocol , utilizing lung expansion and airway clearance, was implemented in order to minimize or prevent lung complications in their ICU patients.

Method:

- All ICU patients received eZ-PAP® or Acapella® QID, either on admission or when extubated
- Respiratory Care Practitioner did complete patient assessment every shift, including CXR and labs
- If any symptoms were present advanced to plan A or B every four hours:
  - Plan A: IPV® or The MetaNeb® System
  - Plan B :The Vest® System with EZ-PAP®
- When noted symptoms resolved, patient graduated back to previous therapies QID, then BID if still symptom free after 72 hours.

Results: Improved Chest X-rays post therapy. Further studies examining protocol impact on ICU LOS are warranted.

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The MetaNeb® System Literature
Respiratory Care - 2006 Open Forum Abstracts

"A Case Study: The Use of MetaNeb® to Improve Secretion Removal and Reverse Atelectasis."
Bocci, M, Garcia, JA, Timon s B. Wolff R, Hargett K, Thornton, C. 2006. AARC Open Forum Abstract. Avail. at: http://www.rcjournal.com/abstracts/2006/?id=OF-06-113

Case Summary:

- 80 year- old male post-op thoracoscopic surgery
- CHFO therapy with bronchodilators was administered every 4 hours via the MetaNeb® System
- During the treatments, patient expectorated large amounts of tenacious secretions
- Within 8 hours of initiation of therapy & after only 2 treatment sessions
  - improvement in breath sounds
  - oxygen decreased to 6 Lpm while maintaining SpO2 of 97-100%
  - Ensuing chest x-rays revealed improved aeration

CHFO bronchial hygiene therapy continued for the duration of the patient's stay in the ICU. Progressive improvement in the patient's pulmonary status was documented

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Literature On The MetaNeb® System In-line Application

Aggressive Pulmonary Secretion Clearance Intervention In a Long Term Care (LTC) : A Treatment Protocol Using The MetaNeb® System

Select Specialty® Hospital – Houston, LP Houston, TX*; Hill-Rom Respiratory Care** ADVANCE FOR LONG-TERM CARE MANAGEMENT | 2011 BY ELIZABETH COLEMAN, BSM, RT; BRIAN BECKER, MED, RRT

- Intubated or trached patients on mechanical ventilation received The MetaNeb® System every 6 hours through the ventilator circuit for 10 minutes
- Continue until weaned from mechanical ventilation, then every 6 to 8 hours until decannulation or until discharge
- Generally, patients continue to require airway clearance after decannulation
  - The MetaNeb® System may be used in these patients, or sometimes changed to another modality such as HFCWO
- Quality improvement results
  - Weaning percentage
  - Decreased bronchoscopies

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New Literature on The MetaNeb® System

Chest High Frequency Oscillatory Treatment for Severe Atelectasis in a Patient with Toxic Epidermal Necrolysis (TEN)

Shiara Ortiz-Puois, MD, Laura P. Boshini, MD, Kathy A. Short, RRT, RN, James Hwang, MD, Bruce A. Calms, MD, Samuel W. Jones, MD
Journal of Burn Care & Research: March/April 2013-Volume 34-Issue 2-p doi: 10.1097/BCR.0b013e318257d83e

- 17 year old girl developed Toxic Epidermal Necrolysis involving > 80% of total body surface
- Electively intubated for pain and wound management on HD 3
- Developed a significant left-sided atelectasis after extubation on HD 17

Example of Toxic Epidermal Necrolysis

[1]http://www.bing.com/images/search?q=free+pictures+of+Toxic+Epidermal+Necrolysis&qpvt=free+pictures

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- Was effectively managed with The MetaNeb® System
- HD 18 - treatments were given every 2-3 hours for 10 mins each
- Within 4 hours of starting the every 2 hour treatments her atelectasis partially improved
- Patient did not need re-intubation
- Her atelectasis completely resolved by HD 21
- Discharged home HD 25 with no further respiratory complications

Example of Toxic Epidermal Necrolysis

[1]http://www.bing.com/images/search?q=free+pictures+of+Toxic+Epidermal+Necrolysis&qpvt=free+pictures

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New Literature on The MetaNeb® System

The MetaNeb® System in an Acute Care Hospital Setting: An Assessment of Impact on Hospital Length of Stay Using A Failure Mode and Effects Analysis.

Travis Grasley, RCP, MA, RRT, Mercy Tiffin Hospital

A 3 month evaluation, January to March 2012, to determine the impact of The MetaNeb® System in hospitalized patients with pneumonia & other infiltrates

- Comparison of the average LOS for
  - 11 patients in The MetaNeb® System treatment group
  - 11 patients in the retrospective study group (with an identical diagnosis)
- The MetaNeb® System patients received aerosol and alternating 2 mins of CHFO and CPEP for a total treatment time of 8 mins

Results:

- The mean LOS observed-to-expected (OE) ratio was calculated for each group
  - Mean LOS OE ratio in The MetaNeb® System group was 0.807 ± 0.502
  - Mean LOS OE ratio in the retrospective group was 1.457 ± 0.752
  - Difference 0.65; 95% CI: 0.075-1.225; P=0.029
- The MetaNeb® System treatment had a statistically significant effect on reducing the mean length of stay OE ratio

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The MetaNeb® System - ICU to Extended Care

Patients on Mechanical Ventilation	• Continuous pulses of positive pressure oscillating airways to mobilizes secretion[1]
Post-extubation management in ICU	• Help prevent respiratory complications related to atelectasis & retained secretions[1]
Floor Therapy	• Prevent or reverse atelectasis and aids in the mobilization of retained secretions[1]
For Extended and Long Term Care	• Enhance secretion removal and help prevent or resolve patchy atelectasis[1]

To Improve Outcomes!

[1]*The MetaNeb® System User Manual (174432 REV 1) page 4 & 6*

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The MetaNeb® System Summary

- Three therapies in one device
  - Lung expansion (CPEP)
  - Airway clearance (CHFO)
  - Aerosol delivery
- Ability to provide supplemental oxygen
- Provides MetaTherapy® Treatment
  - Multiple treatments delivered simultaneously
  - Alternating lung expansion & secretion clearance therapies
  - Maintaining PEP & delivering aerosol throughout treatment

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THANK YOU

You Are In The Best Position To Make The Difference!